Wear and wear measurement in total and hemi hip replacement

Thesis

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LIST OF ABBREVIATIONS

3D Three-dimensional

Al Alumina

AP Anterior-posterior

CI Confidence interval

CoC Ceramic on ceamic

CoCr Cobalt-Chrome

CoP Ceramic on polyethylene

CN Condition number

HA Hemiarthroplasty

HHS Harris Hip Score

ME Mean error

Mm millimetres

MoM Metal on metal

MoP Metal on polyethylene

PE polyethylene

RCT Randomized controlled trial

ROM Range of movement

RSA Radiostereometric analysis

SD Standard deviation

THR Total hip replacement

TPM Total point motion

UHMWPE Ultra high molecular weight polyethylene

LIST OF PAPERS WITH BRIEF SUMMARY

Paper 1

Dahl, J. Figved, W. Snorrason, F. Nordsletten L. Røhrl SM.

The Center Index Method. An alternative for wear measurement with radiostereometry (RSA). *J Orthop Res* 2012; 31(3):480-484

A new method for wear measurement in hemispherical cups is presented. Instead of comparing present stereoradiographs with post-operative ones, we developed a method for calculating the post-operative position of the center of the femoral head on the present examination and replacing this for the postoperative examination. We compared this alternative method to conventional RSA in 27 hips in an ongoing RSA study (Paper 3). We found a high degree of agreement between the methods for both mean proximal (1.19 mm vs. 1.14 mm) and mean 3D wear (1.52 mm vs. 1.44 mm) after 10 years. Intraclass correlation coefficients (ICC) were 0.958 and 0.955, respectively ($p < 0.001$ for both ICCs). The results were also within the limits of agreement when plotted subject-by-subject in a Bland–Altman plot.

Paper 2

Dahl, J. Nivbrandt, B. Søderlund, P, Nordsletten, L. Røhrl, SM.

Less wear with aluminium-oxide heads than cobalt-chrome heads with cemented ultra high molecular weight polyethylene cups. A ten-year follow-up with radiostereometry. *Int Orthop.* 2012; 36(3): 485-90.

87 hips in 84 patients were recruited from two RCTs. All patients were operated with a cemented stem and cup. 51 patients had 10-year RSA examinations of adequate quality for wear measurement. 20 patients had CoCr heads and 31 patients had alumina heads. Linear wear was measured as penetration of the center of the femoral head in relation to the cup. After 10 years the mean (95% CI) proximal penetration for CoCr heads was 0.96 mm (0.68-1.23) and for alumina it was 0.42 mm (0.30-0.53) ($p<0.001$). For 3D penetration, the results were 1.07mm (0.79-1.35) and 0.53 mm (0.38-0.63) ($p<0.001$) respectively. We found a tendency towards more osteolysis and radiolucent lines around the cups in the CoCr group. We found no difference in revision rates or clinical outcome between the groups

Paper 3

Dahl, J. Snorrason, F. Nordsletten, L. Røhrl, SM.

More than 50% reduction of polyethylene wear in uncemented acetabular components using Alumina heads compared to Cobalt-Chrome heads after 10 years. A prospective RSA study. *Acta Orthop* 2013;84(4): Epub 2013/06/26

43 hips in 39 patients were recruited from an RCT. All patients were operated with THR, all patients received an uncemented cup with a conventional PE liner, but on the femoral side three different stems were used. 37 hips had RSA examinations of adequate quality for wear measurements at 10 years. 21 of these had CoCr heads and 16 had alumina heads. Wear was measured as proximal and 3D penetration of the center of the femoral head in relation to the cup. With alumina heads proximal wear (95% CI) after 10 years was 0.62 mm (0.44-0.80) compared to 1.40 mm (1.00-1.80) in the CoCr group ($p=0.001$). For 3D wear the results were 0.87 mm (0.69-1.04) and 1.78 (1.35-2.21) for alumina and CoCr heads, respectively ($p<0.001$). Median (range) HHS was 98 (77-100) in the alumina group compared to 93 (50-100) in the cobalt-chrome group ($p=0.01$). We found no difference in osteolysis or revision rate between the groups.

Paper 4

Figved, W. Dahl, J. Snorrason, F. Frihagen, F. Røhrl SM. Madsen, JE. Nordsletten L.

Radiostereometric analysis of hemiarthroplasties of the hip - a new and highly precise method for measurements of cartilage wear in the human body. *Osteoarthritis Cartilage* 2012; 20(1): 36-42.

22 patients with a displaced femoral neck fracture were included in an RCT to evaluate acetabular cartilage wear after insertion of a bipolar hemiarthroplasty. A phantom model study was performed prior to the clinical study to see if it was possible to use the computed center of the bipolar head to measure wear in the same way as we do in THR. The mean error of elliptical fitting of the bipolar head was 0.024 mm (SD=0.006). Double examinations were performed to investigate the ability to measure zero wear after rotating the bipolar head; the mean difference (95% CI) between double examinations was 0.0195 mm (0.100-0.289) for TPM. In the clinical study, 8-10 tantalum beads were inserted in the pelvis to represent the acetabular segment to which the penetration of the prosthetic head center was measured against. The head migrated 0.62 mm on average up to 3 months and a further migration of -0.07 mm up to one year. We found RSA to be suitable for cartilage wear measurement in hemiarthropasties. We found no significant wear between three and 12 months.

INTRODUCTION

Total hip replacement

Total hip replacement (THR) is a well-documented treatment for a spectrum of diseases in the hip joint[1,2]. There are no exact worldwide statistics on THR, but over one million operations are performed per year[2]. The numbers are doubtlessly increasing, at least in the western hemisphere. 7786 primary THRs and 1299 revision THRs were performed in Norway in 2012[3]. Restoring arthritic and ankylosed hip joints has been tried for more than a hundred years. The first surgical attempt was interposition of the destroyed joint with different tissues, including facia lata, skin and even pig´s bladder. In 1938, the Norwegian emigrant Marius Smith-Petersen implanted his first Vitallium cup (Fig 1)[4] and together with the work of the Judet brothers in France[5] a new era in hip surgery was launched. Parallel to this, attempts were made to replace the hip-joint with large metal heads secured by screws and bolts to the femoral shaft and a matching cup in the acetabulum by Wiles and McKee/Watson-Farrar[6,7]. Moore was the first to fixate the femoral component intramedullary[8]. The next paradigm shift came with sir John Charnley and his concept of low friction torque arthroplasty of the hip consisting of a cemented stainless steel monoblock stem with a 22.25 mm head articulating with a cemented polyethylene (PE) cup[9]. This concept improved the results of THR dramatically and up to 81% survivorship at a minimum of 25 year follow-up of this implant has been reported[10]. The Charnley hip prosthesis is still regarded as the gold standard to which all new implants are compared. Both cemented and uncemented implants are widely used today. In national joint registries, cemented THR have better long-term survivorship than uncemented THR[11].

The reason for this is that uncemented cups historically have performed worse than cemented cups. However, uncemented stems tend to have better survival than cemented stems, at least for aseptic loosening[11,12]. Many surgeons, especially in Scandinavia, have started using a reverse hybrid technique consisting of a cemented cup and an uncemented stem[13]. With modern designs, the problem of short-term implant fixation is more or less solved. The main focus of this thesis is on the articulation. The ideal coupling should provide low wear-rate, durability, excellent bio-compatibility, close to normal range of motion (ROM). Different materials have been tried to accomplish this. Metal and ceramic heads on different variations of PE are still the most used. These are so-called “hard on soft” articulations, referring to the difference in density between the hard head and the relatively softer socket material. Ceramic heads in ceramic liners and metal heads in metal cups are referred to as “hard on hard” bearings. Several other articulations are also in use such as PE on metal in dual mobility cups. Ceramic heads in metal cups and *vice versa* are also in use, though in small numbers. Different concepts have different theoretical advantages and disadvantages.

Figure 1: Left to right; Smith-Petersen mold arthroplasty, Charnley low friction arthroplasty and uncemented THR with CoP bearing.

Wear

A THR is a mechanical coupling where a femoral head articulates with an acetabular component. In all couplings where two surfaces articulate under load, there is a potential for wear. Wear can be defined as 'the progressive loss of material from the operating surface of a body occurring as a result of relative motion at its surface'[14]. During the first months after implantation the wear rate is seemingly relatively high. This is referred to as the "running in" phase of the coupling. The area that actually articulate in this phase is smaller because of uneven surfaces, the area gets larger after asperities on the surfaces are broken down, and the femoral head and the acetabular component articulate smoother. Permanent (plastic) deformation of the PE without loss of material is called creep, and probably accounts for most of the measurable head penetration in the initial phase. "Bedding in" of the PE liner in modular uncemented cups affects measured head penetration in the same way when the metallic shell is used as reference [15]. The wear rate reaches a steady state that can be described by the equation: $V=KFx$, where V is the volumetric wear in mm^3, K is a constant that varies between different material couples (e.g. high in MoP and low in CoC), F is the mechanical force applied on the coupling and x is the distance travelled (i.e. larger heads wear more than smaller[16] and a high level of activity yields more wear[17]). This is true *in vitro* where volumetric wear is measured and all factors are easy to control, but not as obvious *in vivo* where we measure linear wear on radiographs as a surrogate for true volumetric wear and factors like patient weight (F) and activity (x) are variable and less controllable. *In vivo* confirmations of *in vitro* findings through clinical studies are very important, but time- and resource-consuming. Studies of particulate debris show that most particles are in the submicron range and about one million particles are worn off per step or cycle in a bearing that is worn 0.1 mm/year. Mechanical wear can be subdivided in *abrasive, erosive, adhesive* and *fatigue* wear. *Abrasion* is either *two-body*; where asperities on the harder surface cut into the softer material and particles are removed, or *three-body wear* where a fragment of hard material (e.g. bone-cement) is trapped inside the coupling and cut into or gets embedded in the softer material. The magnitude of abrasive wear is relative to the shape, size and hardness of the fragment. *Erosion* (or open three-body wear) is a term used for wear that occurs when fragments within fluid erode the surfaces where there is no contact between the articulating surfaces, this is probably not a major factor in wear of THR. *Adhesion* arises when asperities on both surfaces make contact and the surfaces are moved tangentially on each other. Strong adhesive forces are released in the softer material, it can be deformed and cracks in the material can occur. These lead to removal of fragments and subsequent wear. *Surface fatigue* can occur after the first phase of running-in of the coupling. The bedding-in allows the coupling to transform forces evenly from one surface to the other. This phase is inevitable, but may lead to subsurface cracks. Over time with repeated loading cycles these could develop into characteristic pitting of the surface and thereby loss of material. A more severe mechanism is delamination, where chunks of material can be released from the surface due to subsurface cracks. This is mostly seen in tibial PE inserts in knee replacements, but may also occur in acetabular components in THR. Of these mechanical modes of wear, abrasive wear is the most important in THR because of the multidirectional movement of the hip joint. Wear between objects that were not intended to move in relation to each other (e.g. femoral stem taper and head or femoral stem and modular neck) is also an issue[18,19]. There is still a debate whether this is due to corrosion or mechanical stress on the trunnion, most likely; the mechanism is a combination of the two, called MACC (mechanically assisted crevice corrosion)[20,21]. The hypothesis is that repeated cyclical stress on the head/neck junction induce fracture of the protective oxide layer that lead to an unstable electrochemical environment inside the crevice that leads to corrosion (Fig 2). Corrosion products can get access to the joint space, induce pseudotumor formation, and third body wear of the bearing. This is probably a minor problem in ceramic on PE (CoP) articulations since they are less susceptible to MACC[22]. Kurtz et al. (2013) found less taper fretting corrosion with alumina than CoCr heads in a retrieval study[23]. There is however one report of pseudotumor formation in an CoP coupling[24].

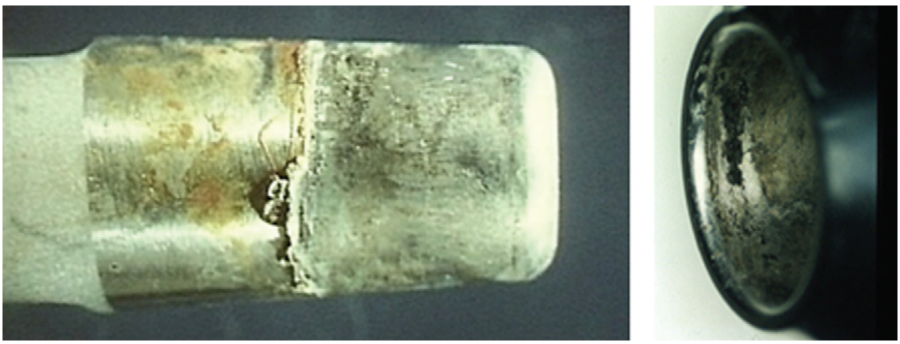

Figure 2: Illustration of wear between the taper of the stem and the prosthetic head. From Biomaterials Sience, Third ed, p 864 © Elsiever

If a PE liner is worn-trough and the head reach the metal shell, we also have a situation where two materials that are not intended to articulate wear against each other. The same would be the situation if a ceramic head or acetabular liner fractures. The latter is a catastrophic complication in THR that inevitably lead to revision surgery. Different biomaterials are used in combination as bearing surfaces in THR, and they show different wear patterns and failure modes.

Bearings in THR

The classic bearing combination in THR is a metal head that is coupled with a cemented PE socket (MoP). Metal heads are cheap, durable and well proven. Cobalt-chrome is currently the most used alloy for femoral heads in THR. When used in combination with a well-documented femoral stem, this articulation show excellent long term results in both single series[25] and registry reports[26]. A metal head can also articulate with a PE liner in an uncemented metal shell. This combination shows inferior results compared to cemented cups mostly due to aseptic loosening of the cup in registry studies[11,27]. Interestingly, one recent review reported a higher wear rate of conventional PE in uncemented cups compared to cemented cups[28]. The reason for this is unclear, and probably multi-factorial. Thinner PE may lead to higher contact stress, and micromovement of the liner in the shell due to poor fit or failure of the locking mechanism may also cause increased wear [29]. The femoral head can also be made of different kinds of ceramics. Ceramic heads can also be used in combination with ceramic liners or ceramic inlays in PE liners and metal cups. Due to their superior wear properties, ceramic-on-ceramic (CoC) articulations show less linear and volumetric wear than any articulation including PE[30]. However, there are some complications to this coupling that does not occur in MoP. CoCs are exposed to fractures of the ceramic head, chipping of the liner and squeaking[31]. A THR can also have a metal-on-metal (MoM) articulation, either as a large diameter femoral head on a femoral stem or a resurfacing THR. MoM articulations have less linear and volumetric wear than MoP, but have other complications such as increased metal ion levels, pain, ALVAL (aseptic lymphocyte dominated vasculitis-associated lesion), loosening, and show high revision rates in registry studies[32]. Both the US Food and drug administration[33] and EFORT[34] have serious concerns with MoM and the use of this bearing has declined dramatically[35]. Dual mobility cups are mostly used in patients with increased risk for dislocation[36]. In this thesis, the main focus is on the wear pattern of CoP compared to MoP. Numerous simulator studies report reduced PE wear with ceramic heads compared to metal heads[37,38]. We are not aware of any clinical studies with a high precision measuring method that confirm this *in vivo* before our studies presented in this thesis[39,40].

Figure 3: Examples of different bearings in THR: From left MoP cemented, MoP uncemented, CoP and CoC (with permission from Stryker)

Polyethylene

Polyethylene is a versatile plastic due to its formability, low surface friction, high impact resistance, good chemical and water resistance, and relatively high melting point (≈ 137 C). PE in the form we use it in THR is Ultra High Molecular Weight Poly Ethylene (UHMWPE). To be defined as UHMWPE, the average molecular weight has to exceed 3.1 million g/mol. Different resins (substrate) are available that meet this standard, currently used are GUR 1020 and GUR 1050 (GUR is an acronym for Granular UHMWPE Rurchemie). PE is a polymer that consists of long strands of repeating CH_2 molecules. The strands are folded in repeating sheet-like crystalline lamellae connected with tie molecules. These sheets are embedded in amorphous regions of the polymer strand. The main ingredients in PE are ethylene gas and hydrogen with titanium tetrachloride as a catalyst. This process yields PE as a powder (resin) that can be molded by compression and heat into blocks or rods of solid PE, or directly into the final shape[41]. PE was the chosen material for Charnley on the acetabular side in his low friction arthroplasty from 1962 and remains the mainstay in modern THR[42]. A lot of resources have been put into improving the wear resistance of PE. Until the mid-nineties, PE was sterilized by ϒ-radiation in air. Gamma rays used for sterilization break down the polymer-chain by so-called chain scissoring; leaving free radicals that can readily react and form cross-links between the polymers or react with oxygen and cause oxidation. Unfortunately, the latter is the most likely reaction if the irradiation takes pace in an aerobic environment. This oxidation degrades the mechanical properties of the PE and thus the wear resistance[43]. Oxidation of PE can occur both during the irradiation and later if packed and stored in an oxygen-containing environment[44]. Oxidation may even take place when PE is exposed to the oxygen-containing environment of the human body[45], even though the oxygen-tension is low inside the hip joint. To avoid the unwanted oxidation, manufacturers changed sterilization and packing methods[46]. PE can be sterilized by ethylene oxide (EtO), which is a highly toxic gas that eliminates bacteria, virus and spores efficiently[47]. Gas plasma sterilization is another sterilization method that doesn't include radiation; it relies on surface sterilization by ionized gas to break down biological organisms[48]. Both methods offer excellent sterilization and do not affect the mechanical properties of the PE. The fact that the PE is not irradiated and thereby is not subject to formation of free radicals also eliminate cross-linking of the polyethylene. The latter is negative as cross-linking of PE enhances the resistance to wear[49]. Another method to avoid oxidation is to irradiate the PE in an anaerobic or low-oxygen environment and pack it in an inert environment (e.g. argon or nitrogen gas) to avoid shelf-oxidation. There is still a risk for oxidation during storage if the packing is permeable to oxygen[44], and the long-term impact of *in vivo* oxidation is not clarified[45]. Gamma irradiation has been used as the method of choice for sterilization of PE since Charnley´s pioneering work; more or less accidentally the cross-linking came as a bonus. A dose of 2.5 Mrad was used for sterilization purposes. As the quest for increased wear resistance evolved, manufacturers increased the irradiation dose to 5-10 Mrad to increase the amount of cross-linking. High doses of irradiation yields a higher resistance to wear, but reduced mechanical properties[50]. To eliminate the free radicals, the PEs are thermally treated by either annealing (sub-melt) or re-melting.

Annealing preserve the mechanical properties better than re-melting because the crystalline structure of the PE is kept intact, but does not eliminate the free radicals to the same extent as re-melting[51]. However, there is no reported difference in clinical outcome between these thermal treatment methods [52] and annealing also seems safe[53]. Adding an antioxidant (vitamin E) either by postconsolidation by soaking the implant in a vitamin E-containing solution or preconsolidation by adding of vitamin E to the resin, is used by some companies to stabilize the free radicals without post-irradiation re-melting. This is believed to reduce the trade-off of reduced mechanical properties for increased wear resistance. In general, cross-linked PE has superior wear properties compared to conventional PE[54,55].

Head materials

Metal heads

Different metal alloys are the most used material for femoral heads in THR. They are in general durable, cheap and well documented. Metal alloys have desirable material features such as high strength (fracture resistance), hardness, relative corrosion resistance, formability and biocompatibility. The concern of polyethylene wear-debris in the 1990s started the quest for less wearing (smoother, harder and more wettable) surfaces on the femoral side. This was also encouraged by the trend towards larger-diameter heads to increase ROM and protect against dislocation[56]. However, a well-known side effect of upsizing femoral heads is increased wear[57]. Surface treatment and surface modification of metals are areas of ongoing research. One unwanted side effect of large metal heads is increased wear and corrosion at the trunnion between the stem and the head[18,19]. This has led to several attempts to improve corrosion resistance of metals by alterations of their composition. These include changing the contents of the alloys and applying different surface treatments. Different alloys have different material characteristics.

Cobalt-Chrome

Many CoCr alloys are available, but a molybdenum-containing variant (CoCrMo) is predominantly used in femoral heads[58]. This alloy typically contains 61-66% Cobalt, 27-30% Chrome, 4,5-7% Molybdenum and less than 2% Nickel, Iron, Manganese, Carbon and Silicon. This is a hard, strong and corrosion-resistant alloy that is well suited for femoral heads. CoCr has a long track record as the predominant bearing couple with PE in THR and are therefore clinically proven to be safe. Femoral heads made of CoCr release metal ions, but this release seem to be negligible in MoP bearings compared to MoM bearings [59]. Several manufacturers have applied surface treatment of CoCr heads to enhance their wear properties. CoCr is still the most used material for femoral heads.

Titanium alloys

Titanium alloys are widely used in orthopaedic implants. CPTi (Comercially pure Titanium) contain 98-99.6% titanium and traces of iron and carbon. It is highly corrosion resistant and has high ductility (formability). These are desirable features for some applications (e.g. porous coating and fiber mesh on metal cups). Ti6Al4V is the most used Titanium alloy in THR. It contains 89-91% Titanium, 5.5-6.5% Aluminum, 3.5-4.5% Vanadium and less than 1%

Carbon. Titanium alloys are corrosion resistant because they are protected by a film of oxides (TiO_2). This passive metal-oxide layer develops when titanium is exposed to oxygen and reduce the exposure of metal ions to body fluids and hence corrosion. The Achilles-heel of Titanium alloys is their relative softness compared to CoCr and stainless steel thus lower scratch and wear resistance. Attempts to harden the surface of Titanium alloys include ion-implanting and various nitriding techniques. The main concern of such coatings is their longevity and that one might see accelerated wear if the coating is damaged or worn. Ti alloys are currently not commonly used for femoral heads.

Surface modified metals

Smith and Nephew (Memphis, USA) have developed their own biomaterial for femoral heads, Oxinium. This is a zirconia (97.5%) Niobium (2.5%) alloy that is heat-treated in the presence of oxygen, so the surface layer is an oxidized zirconia ceramic. Desirable features of this process are a high degree of wettability, smoothness and scratch resistance. The problem of phase transformation is smaller than with conventional zirconia as 95% of the zirconia is in a stable monoclinic phase. The wear properties of Oxinium is reported to be better than conventional CoCr heads *in vitro*[60], but this was not confirmed *in vivo*[61]. Stryker (New Jersey, USA) have developed the LFIT technology (Low Friction Ion Treatment). This is a process to enhance the frictional properties of CoCr. Nitrogen ions are embedded in the metallic surface of femoral heads under high energy. This process hardens the surface and increases the wettability of the femoral head. This effect seems to decrease over time, but no adverse effects to LFIT has been reported in a retrieval study[62]. One study report 28% wear reduction with LFIT heads compared to standard heads on the same PE up to three years[63]. No long-term follow-ups with a high precision measuring method have been reported.

Stainless steel

Stainless steel is a term used to describe several iron-based alloys; such alloys have been used in orthopaedic implants for more than 50 years. The most used is termed 316L and contain 61-68% iron, 17-19% chrome, 10-15.5% nickel, 2-4% molybdenum and less than 2% nitrogen, copper, tungsten, carbon and silicon. It is important to keep carbon levels as low as possible to avoid formation of carbides that reduce corrosion-resistance. The “L” in 316 L denotes the low carbon levels of these alloys. Stronger and more corrosion resistant alloys (e.g. Ortron) have been in use since the 1980s. Alloys with reduced nickel content (e.g. BioDur) have been developed as a consequence of the focus on allergic reactions to nickel. Stainless steel is, however, less corrosion resistant than CoCr and titanium. Despite an excellent long-term track record as a bearing couple for PE in THR, the use of stainless steel heads is decreasing.

Ceramic heads

The currently used ceramics consist of alumina (Al_2O_3) and zirconia-toughened alumina. All ceramics are processed under strict regulation by sintering of the ceramic powder after it has been pressed into the desired shape, and then subjected to isostatic pressure to reduce porosity. The “raw” head is then machined and polished to improve the surface finish. Ceramics are by nature brittle and may therefore fracture. The fracture risk is related to the grain type, size and shape. The purity of the ceramic powder and the homogeneity of the composite are also factors that affect the brittleness of the ceramic. Over the years, manufacturers have reduced the grain size and refined the manufacturing process to reduce the fracture risk. Theoretical advantages of ceramic femoral heads compared to metal heads include their superior hardness that leads to scratch resistance (e.g. *third body wear)*. In addition, scratches on ceramic heads form “valleys”, while scratches on metal heads form “valleys and peaks” and these valleys seem to be more forgiving in relation to wear. Ceramic heads are more wettable (Fig 4), and this increases the lubrication and hence reduce the friction of the articulation. Ceramics are bioinert and not corrosive. Ceramic materials have been used in femoral heads since the 1970s in CoC bearings[64]. Shikata et al. introduced the CoP bearing in 1977[65], and since then it has been widely used and well documented[66].

Figure 4: Picture showing difference in wettability between ceramic and CoCr heads, Courtesy CeramTec

Alumina

Alumina (BIOLOX®*forte*) is by far the most used ceramic for femoral heads in CoP and CoC bearings. Except for the fracture risk, alumina has excellent tribological properties compared with metal heads. The high degree of wettability increases the lubrication of the coupling. This, together with increased surface smoothness, lowers the coefficient of friction. Alumina heads are four times as hard as CoCr heads, and hence they are more scratch resistant. Alumina is bioinert and stable in humid environments and they do not corrode or discharge metal ions. Fracture of alumina heads have mainly been a problem in CoC bearings, but have also been reported in CoP bearings[67]. Up to 13.4% alumina fractures has been reported in one series[68], but with the use of contemporary alumina heads the fracture rate is reported to be 0.004-0.015%[69]. A fracture of a femoral head is a catastrophic complication to a THR and inevitably leads to revision surgery. These operations are challenging both surgically and with regard to implant choice[70]. Clinical failures of alumina heads led to the quest for stronger ceramics and the development of zirconia heads.

Zirconia

Zirconia is a mechanically stronger ceramic than alumina. It was introduced on the market for orthopaedic surgery in 1985. It is a more complex and less stable ceramic than alumina. Under a combination of temperature, pressure and humidity as for example in the human hip, the tetragonal phase of zirconia can undergo a phase transformation to the monoclinic phase. This changes the volume and mechanical properties of the ceramic. Some studies suggest that local phase transformation lead to surface roughening and accelerated wear over time. To avoid this phase transformation, most zirconia heads were stabilized with magnesium or yttrium. However, from 2000 the biggest manufacturer, Desmarquest (France), started to receive an increasing number of fracture reports of their Y-TZP femoral heads from specific batches produced in 1998. This corresponded in time with a change in the production line of the femoral heads from batch furnace to a continuous tunnel furnace. The manufacturer recalled all heads from these batches, and later the FDA and other regulatory agencies warned against the use of Y-TZP heads produced after the change in production. From August 2001, the company stopped the production of Y-TZP femoral heads. This incident highlights the need for thorough testing of all surgical implants after even seemingly minor changes in design or production method.

Zirconia toughened alumina

Recognising the problem of the brittleness of alumina, the largest manufacturer of alumina heads (CeramTec, Plochingen, Germany) introduced a new ceramic on the market in 2000. The new material (BIOLOX®*delta*) is a zirconia toughened alumina matrix composite (ZTA). This ceramic consists of an alumina matrix (82%) that is reinforced with zirconia (17%) and added 0.5% strontium aluminate (SrAl) and chromium oxide (CrO). SrAl and CrO form mixed oxide platelets that act as crack shielders and phase stabilisators of zirconia. *In vitro* studies are promising[71], but there is no clinical documentation so far of this material with more than two years follow-up[72]. ZTA is increasingly used, especially in CoC articulations.

Osteolysis

William Harris wrote a landmark article in 1995: "The problem is osteolysis"[73], and this statement is still valid. It is not the wear *per se,* that leads to aseptic loosening and failure of THR, but the bone loss due to the host reaction to wear debris. Historically, the reason for osteolysis was thought to be an adverse reaction to acrylic bone-cement and termed "cement disease"[74]. It later became evident that this phenomenon also applies to uncemented implants[75]. It is now a general consensus that the reason for periprosthetic bone-loss (osteolysis) is a low-grade inflammatory response to wear debris that disrupts the local bone homeostasis[76]. Osteoblasts (anabolic) and osteoclasts (catabolic) are the key contributors to this equilibrium. The regulation of the activity of these bone cells is complex and in part still unclear[77]. Macrophages have a central part in the development of osteolysis. Their reaction to particulate debris is phagocytosis and secretion of pro-inflammatory mediators such as interleukins (IL1, IL6), prostaglandins (PgE_2) and tumour necrosis factors (TNF_α) that trigger the immune system and the inflammation process. Macrophages can differentiate into giant cells and osteoclast-like cells. RANKL and osteoprotegrin are also potent factors in the osteolytic cascade. Several intracellular enzymes such as metalloproteinase and collagenase break down bone directly. Cathepsin-k is a unique peptidase that seems to play a key role in bone degradation and is expressed in high levels in osteoclasts The osteolytic lesions can manifest as radiolucent lines around the implants or as cystic lesions that are visible on plain radiographs. The magnitude of the inflammation and osteolysis caused by wear debris relates to the *particle load*: Both the total volume, the amount, and the size of the particles that are accessible for phagocytosis are important. The shape of the particles is also important; it seems that long, fiber-shaped particles are more pro-inflammatory than spherical ones after phagocytosis[78]. The material of the particles may also affect the inflammatory response, and it seems that metal particles induce more inflammation than PE and ceramic particles do[79]. Patients may have different tolerance for wear particles before significant bone loss occurs; this is at least evident for metal debris. Another topic that is much discussed in the development of osteolysis is the impact of joint fluid pressure[80] in the effective joint space (the area where soft tissue and bone is exposed to joint fluid after THR)[81]. An integration of the particle and fluid induced osteolysis theories may be that the low-grade inflammation due to particles leads to increased fluid production and thus high pressure which causes osteolysis.

Wear measurement methods

Assessing the amount of wear in THR is important as wear is closely linked to osteolysis and implant loosening. The most accurate method is to measure the amount of material loss from the PE liner. Unfortunately, this can only be performed in vitro either in wear simulator studies or in direct measurements of retrieved implants. Clinicians have to use a surrogate for material loss when they report wear rates in THR follow-ups. Reduction of PE thickness, often described as linear wear, is mostly used. Different radiological methods are used to measure linear wear. Common for these methods is that they measure the distance of prosthetic head penetration in the acetabular component. Over the years, both manual and computer-assisted methods based on plain radiographs, stereo-radiographs and CT examinations have been developed for wear measurements.

Manual methods

Charnley introduced methods for wear measurements on plain AP radiographs in the seventies. In the first method[82], they simply calculated the femoral head penetration in relation to the metal wire in the cup on the most and least worn parts and divided this by two. They later refined the method by adding postoperative examinations[83]. The position of the femoral head on the follow-up was compared to the position postoperatively, and the difference

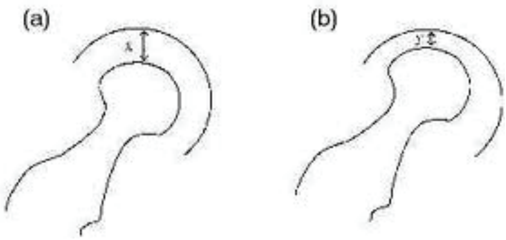

Figure 5: The Charnley and Cubic method. (a) postop, (b) at follow-up.

was defined as wear (Fig 5). An obvious shortcoming of these methods is that they do not take into account the orientation of the cup that affect the position of the metal wire and hence the wear rate. The error of these methods are reported to be too large to make them useful in follow-ups of patient series [84]. Another manual method was introduced by Livermore in 1990[85]. His method was to define the center of the femoral heads with templates and then measuring the shortest distance to the outer surface of the cup with a compass (Fig 6). This radius represents the most worn area. The thickness of the cup in this area is measured and is compared to the postoperative thickness, and the difference is defined as linear wear. Wear measurements with the Livermore method has been compared with measurements on retrieved cups and it has been found that this method has sufficient accuracy for routine wear measurements in the clinical setting[86]. The strength of this method is that it only requires plain AP radiographs and templates to locate the center of the prosthetic head to measure wear.

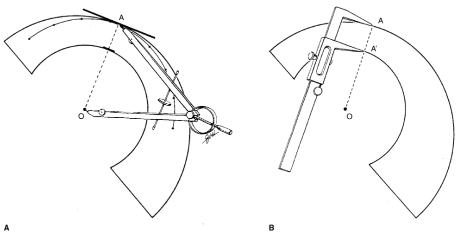

Figure 6: The Livermore method

Computer-assisted methods

Several methods for automated wear measurements on plain radiographs are reported and currently in use. The Martell method (Hip Analysis Suite)[87] and the Devane method (Polyware)[88] use an edge detection technique to calculate the distance and the direction of femoral head penetration in relation to the cup. This can be done either in 2D using regular AP radiographs, or in 3D by adding cross-table lateral radiographs. The precision and accuracy is generally better than manual methods, and new algorithms and improved edge detection are developed to improve them further[89,90]. Generally, wear measurements are better for 2D than 3D measurements due to poor quality of the lateral radiographs[91]. In fact, one publication by Stilling et al. (2010)[92]

states that using Polyware on just one radiograph is sufficient for clinical evaluation of PE wear in medium to long term follow-up of conventional PE liners in 2D. It might not have the precision and accuracy needed to evaluate more wear-resistant cross-linked PE.

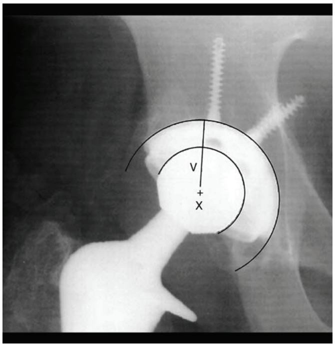

Figure 7: The Polyware method

Radiostereometric analysis (RSA)

RSA is a highly accurate and precise method for measurement of relative motion between two segments or one point and a segment in vivo. The method relies on stereoradiographs (i.e. two simultaneous exposures of the same area), skeletal and implant-markers, and a calibration cage. RSA has multiple applications in orthopaedic surgery such as bone growth, joint stability, joint kinematics, fracture healing, implant stability and wear of implants and cartilage. RSA is based on the Work of Selvik[93] and later Kärrholm et al.[94]. It is a time and resource-consuming method reserved for research centres, though new software and introduction of marker-less and model-based methods gradually make RSA studies less resource consuming. RSA is described in more detail in the methods chapter of this thesis.

CT based methods

CT technology has improved substantially during the last years allowing higher resolution images with less metal artefacts at lower radiation doses. This is encouraging since CT has the potential to provide excellent 3D imaging (implant orientation, relation to bone and distribution of osteolytic lesions) and also wear measurements[95,96]. There are still no *in vivo* reports in the literature on wear measurement. The methods will have to be validated, and preferably controlled against retrieved implants[97]. CT based methods may in the future have the potential to provide more information than RSA with the same accuracy, and with a much better availability.

Wear in hemi hip arthroplasty

Hemi hip arthroplasty (HA) has been proved advantageous over internal fixation (also kown as screw fixation or osteosynthesis) in elderly patients with displaced femoral neck fractures[98]. Both unipolar and bipolar HA are in current use. In the Norwegian hip fracture registry, less than two percent of HA for displaced femoral neck fractures are unipolar[99]. The femoral stems can be fixated both with and without bone cement. In Norway there has been a trend towards the use of cementless fixation in recent years and 36% of the stems in HA were uncemented in 2012[99]. Leonardson et al. (2012) advocates the use of cemented stems and to some extent unipolar HA in a study from the Swedish hip arthroplasty register 2005-2010[100]. In a HA, the prosthetic head articulates against the patients native cartilage instead of an implanted cup in a THR. Bipolar HA also have an articulation between the head on the femoral stem and the femoral head prosthesis, this is typically a MoP-bearing, susceptible to PE debris formation and osteolysis[101]. Quantification of this PE wear *in-vivo* is to my knowledge not performed due to methodological difficulties and hence relies on retrieval analyses. Interprosthetic dislocation of a bipolar HA due to excessive PE wear are rare, but some cases are reported in the literature[102]. Wear of the outer articulation (the prosthetic head and the acetabulum) in HA is more thoroughly investigated with focus on cartilage degradation and *protrusio acetabuli.* Different measuring methods have been presented. Kim et al. (2012) reported an annual wear rate of 0.34+/- 0.35 mm in 134 HA at an average of 7.9 years with a manual method. They measured the migration of the center of the prosthetic head to a line through the teardrops on an AP pelvic radiograph[103]. Moon et al. (2008) reported an annual wear rate of 0.23 +/- 0.11 mm in 65 HAs after an average of 51.2 months. They used a modification of the Martell method on standard AP radiographs, replacing the circumference of the acetabular shell with three fixed points in the patient's pelvis. The software calculated a circle from these points and the migration of the femoral head prosthesis was measured in relation to this circle[104]. Jeffcote et al (2008) presented the first RSA study on cartilage wear after HA. They compared wear patterns of unipolar and bipolar HA with a cemented double tapered polished stem. They found more wear in unipolar than bipolar HAs, 1.52 mm vs. 0.62 mm in 18 patients after two years. Wear was expressed as total point motion (TPM) of the center of the femoral head prosthesis along the cardinal axes, in relation to implanted skeletal markers in the supra-acetabular trabecular bone.

AIMS OF THE STUDIES

In the first paper we developed a new method for wear measurements with RSA. We investigated whether it was possible to perform wear measurements with RSA without previous stereoradiographs and tantalum markers. This method was compared to conventional RSA measurements of the same material. In the second and third paper we investigated wear-patterns of alumina and cobalt-chrome femoral heads against conventional polyethylene in a long-term clinical setting. Other clinical and radiological outcome measures that were investigated in these papers were: revision rates, Harris hip score (HHS), and the distribution of osteolytic lesions around the cup. In the fourth paper we developed a method to measure in vivo cartilage wear with RSA after hemiarthroplasty for displaced femoral neck fractures.

PATIENTS AND METHODS

Patients

Paper 1

Patients in this study were recruited from the same material as paper 3. 27 patients met the criteria for inclusion in this study.

Paper 2

Patients in this study were recruited from two on-going RCTs[105,106].

The first study was designed to compare the Scientific Hip Prosthesis (SHP) and the Lubinus SP2 prosthesis using RSA[106]. 38 of these patients had 28 mm CoCr heads and made up one of the groups in our study. The second group was recruited from a study designed to compare a low monomer bone cement (Cemex) with Palacos bone cement[107]. All patients in this study received a 28 mm Alumina head and made up the second group in our study (Table 1). Inclusion criteria were primary osteoarthritis in both studies. In the first study, patients were stratified by gender. Patient demographics did not differ between the studies.

Figure 8: Implants in paper 2: Left: SHP cup (top), Lubinus cup (bottom) SHP (left) and Lubinus stems

Table 1: Description of patients, groups and follow up in paper 2

Head material		Cobalt-Chrome		Alumina	
Prosthesis		SHP	SP2	SP2	
Cement		Palacos		Palacos	Cemex
Included (hips)		40		44 (47)	
Age at operation (Range)		67 (55-78)	67 (52-78)	65 (51-76)	70 (51-81)
Gender (Male / Female)		8 /12	8 / 12	10/14	9/14
Weight at operation (Range)		70 (48-100)	71 (53-92)	68 (53-96)	70 (53-95)
Preoperative HHS (Range)		39 (15-57)	42 (23-61)	47 (29-71)	48 (17-64)
Randomized		20	20	24	23
Excluded		1	3	1	0
Index RSA		19	17	23	23
Drop-outs at 10 years	Dead	7	5	6	4
	Revised	1	0	1	1
	Did not meet	0	3	1	3
10 year RSA		11	9	15	16

Paper 3

Patients in this study were recruited from an ongoing RCT designed to evaluate a new femoral stem design (Epoch) and compare it with both an uncemented stem (anatomic) and a cemented stem (Anatomic option) [108]. Patients with primary and secondary osteoarthrosis of the hip with no gross anatomical abnormalities were included. Due to a withdrawal of the approval to use Alumina heads on Anatomic option and Anatomic stems, patients were operated with a mix of Alumina and CoCr heads and this gave us the opportunity to compare the wear behaviour of these heads against the same acetabular component (Trilogy).

Figure 9: Implants in paper 3. Top: Left to right: Epoch, Anatomic Option and Anatomic stems, Alumina and CoCr heads. Bottom: Trilogy shell and PE liner

Table 2 Description of patients, groups and follow up in paper 3

Head material		Cobalt-Chrome	Alumina
n		23	20
Age at operation (range)		60 (53-72)	64 (34-70)
Gender (M/F)		6/17	9/11
Weight at operation (range)		70 (58-98)	78 (51-95)
Preoperative Harris hip-score		52 (28-69)	55 (25-67)
Side (left / right)		11/12	8/12
Cup size (range)		52 (48-60)	54 (50-60)
Liner thickness (range)		7.3 (6.3-10.4)	7.3 (7.3-10.4)
Stem type	Epoch	0	11
	Anatomic option	14	4
	Anatomic	9	5

Paper 4

Three patients in this study were recruited from a RCT[109], and 19 patients were recruited solely for this study. Inclusion criteria were patients 65 years and older with a dislocated intra-capsular femoral neck fracture. Exclusion criteria were malignant disease, ongoing infectious disease, previous symptomatic hip disease and inability to walk without aids before the fracture. Patients were randomized to receive a cemented (Spectron EF) or an uncemented (Corail) stem. All patients received a 28 mm CoCr head and the same bipolar head (Mobile cup).

Figure 10: Implants in paper 4: From left: Corail stem, Spectron EF stem, Mobility cup, and CoCr head

Table 3: Description of patients, groups and follow up in paper 4

Fixation method	Cemented	Uncemented
n	11	11
Age at operation (SD)	78,4 (7.1)	78.2 (7.7)
Sex		
Weight at operation (SD)(kg)	68.9 (8.9)	66.2 (13.6)
Preoperative HHS (SD)	94.0 (5.5)	96.4 (4.5)
Preoperative BI of 19 or 20 (%)	11 (100)	11 (100)
Bipolar head size (SD)(mm)	48.1 (2.7)	47.0 (2.4)
Eligible for RSA at one year	7	7

Methods

Clinical evaluation

Harris hip score

Patients in all studies were scored with the Harris Hip Score (HHS)[110]. This is a widely used outcome measure after THR. HHS is a clinician-scored outcome measure with high reliability both for different examiners and for repeated testing of the same examiner[111]. The validity of the score has been tested by comparing it to other scores (WOMAC and SF-36) and no major difference was detected[111]. The responsiveness (ability to detect change) of HHS has been evaluated in series of both THR and HA[112,113] and found to be very good at least for short-term follow-ups. HHS has a range from 0 to100. A score of 100 indicates a pain-free hip with normal ROM that does not affect daily activities. In our institution we tend to use a HHS of 60 as a cut off for indication for performing a THR. The score is subdivided in pain score (0-44), walking ability (0-33), activity score (0-14), and an evaluation of ROM and absence of deformity (0-9). According to Marchetti (2005), a postoperative HHS<70 is considered poor, 70-80 is fair, 80-90 is good and >90 is excellent[114]. Since HHS was not performed in one of the groups at the final follow-up, a telephone interview was performed and hence the functional scores were omitted[115].

Barthel index

Patients in paper 4 were scored by Barthel index (BI)[116]. BI ranges from 0-20. A score of 20 indicates that a person is able to live without care and attendance. BI focuses on the ability to perform basic activities of daily living and consists of 10 questions. This is a useful screening for the geriatric population and is found to be appropriate for follow-ups of patients with femoral neck fractures[113]. BI is a clinician scored outcome measure.

EQ-5D

EQ-5D is a questionnaire to measure health related quality of life. It consists of two parts. The first part consists of five questions where the respondent reports his or her level of mobility, self-care, ability to perform usual activities, pain and psychological status. Each of the five questions has three possible answers. The second part is a visual analogue scale ranging from 0-100. Zero is "worst possible health state" and 100 reflects "best possible health state". The respondents indicate on the scale their own evaluation of their overall health state. Based on the scores from the five questions, an EQ-5D index is calculated from a large reference population. Several index populations are available, and the calculated index scores will differ accordingly. EQ-5D is also found to be suitable for follow-up of patients after HA[113]. Ranstam (2011) has pointed out methodological weaknesses in this index and problems with interpretation of clinical results with this score[117]. In contrast to the above, this is a patient reported outcome measure (PROM).

Radiography

Conventional radiography was used in paper 2 and 3. Radiographs were acquired at the 10-year follow-up in both studies. We used mdesk (mdesk, RSA biomedical, Umeå, Sweden) to measure cup position, radiolucent lines (RLL) and osteolytic lesions in the periacetabular bone on AP films. This software was primarily made for preoperative templating of THR, but also has a research edition for postoperative measurements that allows us to determine cup position in relation to pelvic landmarks and measurement of RLL and osteolytic lesions (Fig. 11).

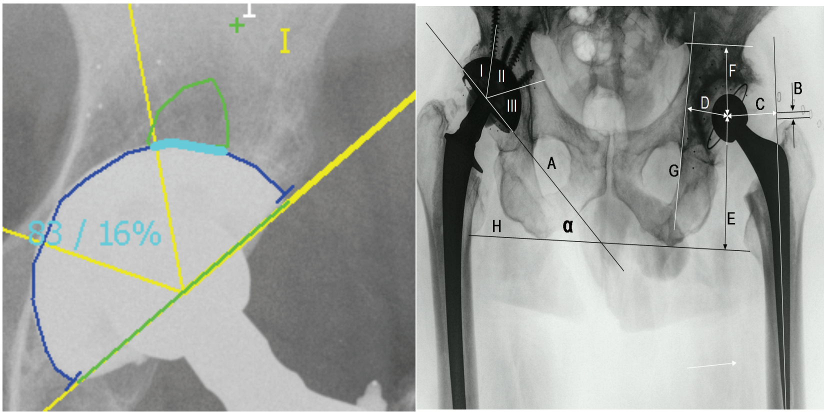

Figure 11: Left: Measurement of Radiolucent lines and osteolytic lesions. Right: Cup positioning in relation to pelvic landmarks

Radiostereometric analysis (RSA)

In marker-based RSA studies of THR, the method relies on 0.8 or 1.0 mm spherical tantalum markers. These markers are implanted in the periprosthetic bone, the cement mantle and mounted on the implants. 6 to 9 markers are typically used in bone segments and 3 to 6 markers on the implants. The center of the femoral head is calculated and used as a point (marker). Each set of markers makes up a segment. Stereoradiographs are acquired postoperatively with the films mounted in a calibration cage (Fig 12).

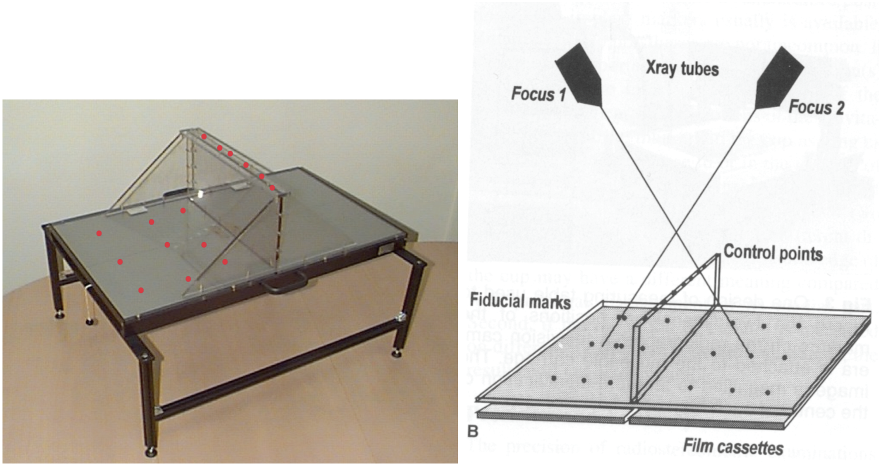

Fig 12: Left: Calibration cage with fiducial markers (bottom) and control points (top). Right: Schematic drawing of set-up

The cage consists of fiducial markers (tantalum beads) that are incorporated in the cage-top and control points (tantalum beads) that are mounted on the ridge between the two film cassettes. These markers are used to construct a virtual 3D coordinate system. Fiducial markers, control points and at least 3 markers in each segment have to be visible in both radiographs to be used for segment motion measurements. The investigated area (e.g. hip) is placed in the area where the x-ray beams intersect (fig 12). Model based RSA does not rely on markers on or incorporated into the implants. Models of implants are created either from laser etchings of real implants or computer drawings from the implant manufacturer. The software recognizes these models and their position can be projected in the 3D coordinate system in the same way as segments made up of markers. Hemispherical objects such as the cup investigated in paper 1 and 3 and the bipolar head in paper 4, can be marked and recognized as a segment or its center can be calculated (marker-less).

Model based RSA is user-friendly with fully automatic recognition of the implant (segment) in the latest software versions of UmRSA. RSA is regarded as the gold standard for measuring migration and wear in THR. To achieve measurements of adequate quality, all steps have to be performed meticulously. The tantalum beads have to be well fixed and this is controlled by the *mean error of rigid body fitting* (ME). This is the mean difference between the relative distances between markers in a segment compared to that of another examination. It is generally accepted that the ME should be less than 0.35 mm in subsequent examinations[118]. The distribution of the markers in a segment is of importance for the quality of the examination. Markers should have a reasonable spread along all three axes to represent a well-defined rigid body. The *condition number* (CN) describes this distribution numerically. A low CN denotes a good distribution of markers in a segment, whereas a high number the opposite. Segments with CN below 110 are regarded to be very reliable, but up to 130-150 can be accepted[118]. The *precision* of RSA examinations is evaluated with repeated examinations of the same patient. The precision describes the method´s ability to reproduce the same result at two examinations with only a repositioning of the patient in between. The precision of RSA should always be reported in clinical studies. It is calculated as the absolute value of the difference between examinations and presented either as in paper 2 as the absolute mean difference and1.96 times the standard deviation of the mean or as in paper 1,3 and 4 as the mean of absolute value for the differences with a 95% CI of the mean difference.

SUMMARY OF RESULTS

In **paper 1** we found that the *center index method* that we developed for wear measurement agreed well with conventional RSA. The mean difference between the methods was 0.046 mm for proximal wear and 0.079 mm for 3D wear. The 95% CIs for measurements were highly overlapping for both proximal and 3D wear between the groups. Intraclass correlation coefficients were 0.958 and 0.955 respectively for proximal and 3D wear and p-values were below 0.001. Probability plots and Bland-Altman plots demonstrate how well the methods agree in a visual manner. All measurements except one were inside the limits of agreement in the BA plots.

Table 4: Comparison of wear measured with conventional and center-index RSA at 10 years in mm (95% CI) for all 27 patients

	Conventional RSA	Center-Index RSA	Mean difference	SD difference	Intraclass correlation coefficient	p-value for the ICC
Proximal wear	1.19 (0.85-1.53)	1.14 (0.77-1.51)	0.046 (-0.058-0.15)	0.26	0.958 (0.911-0.981)	<0.001
3D wear	1.52 (1.15-1.89)	1.44 (1.04-1.85)	0.079 (-0.036-0.19)	0.29	0.955 (0.906-0.979)	<0.001

In **paper 2** we report reduced wear with alumina femoral heads compared to cobalt-chrome heads measured with RSA in cemented cups. Proximal wear (95% CI) was 0.42 mm (0.30-0.53) in the Al group and 0.96 mm (0.68-1.23) in the CoCr group after 10 years (p=0.001). For 3D wear the results were 0.53 mm (0.38-0.63) and 1.07 mm (0.79-1.35) respectively (p=0.001). The distribution of osteolytic lesions was investigated on plain radiographs. We found a tendency towards more osteolysis in the CoCr group. We found no difference in clinical outcome.

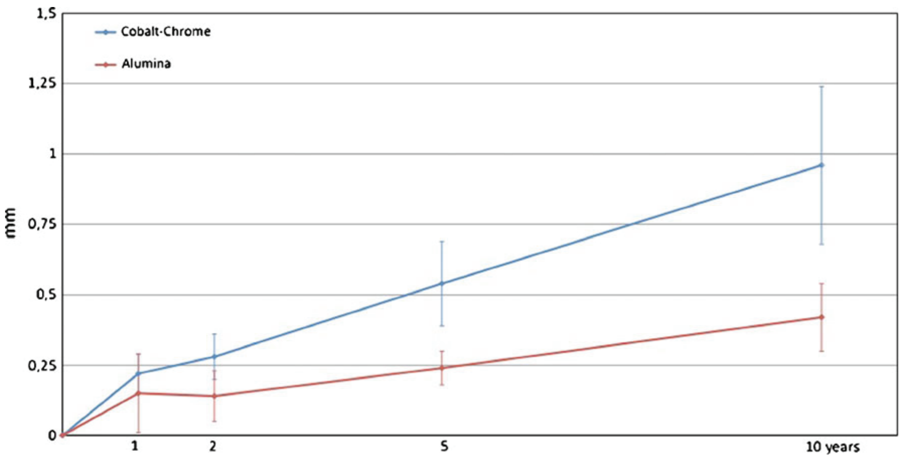

Figure 13: Proximal wear (95% CI) up to ten years for articulations with alumina and CoCr heads

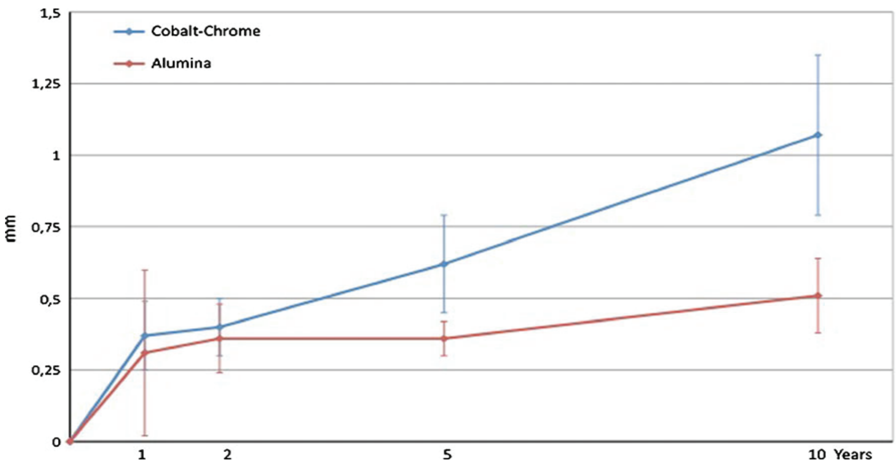

Figure 14: 3D wear (95% CI) up to ten years for articulations with alumina and CoCr heads

Paper 3 confirms the findings of paper two, but in uncemented cups. With alumina heads proximal wear (95% CI) after 10 years was 0.62 mm (0.44-0.80) compared to 1.40 mm (1.00-1.80) in the CoCr group (p=0.001). For 3D wear the results were 0.87 mm (0.69-1.04) and 1.78 (1.35-2.21) for Al and CoCr heads, respectively (p<0.001). We found no difference in osteolysis or revision rate between the groups. Median (range) HHS was 98 (77-100) in the alumina group compared to 93 (50-100) in the cobalt-chrome group (p=0.014). The material is too small to conclude that there is a difference in clinical outcome between the groups up to 10 years.

Table 5: Mean migration of the center of the prosthetic head in relation to the cup in mm (95% CI)

Direction	cobalt-chrome	alumina	Significance
Proximal (y-axis)	1.40 (1.00-1.80)	0.62 (0.44-0.80)	P=0.001
Medial (x-axis)	-0.38 (-0.72- -0.04)	-0.10 (-0.27- -0.08)	P=0.15
posterior (z-axis)	-0.59 (-0.84- -0.34)	-0.32 (-0.54- -0.10)	P=0.10
3D (vector of xyz axes)	1.78 (1.35-2.21)	0.87 (0.69-1.04)	P<0.001

Paper 4 demonstrates that RSA can be used to measure cartilage wear in the acetabulum after HA. A phantom study confirmed that movement of the bipolar head inside the acetabulum did not affect the relation between the center of the head and skeletal markers in the pelvis. A clinical study was performed and revealed no difference between cemented and uncemented femoral components regarding wear. As expected there was a “bedding in” phase of the bipolar head. Mean migration was 0.62 mm (95%CI: 0.27 to 0.97) the first 3 months. Between 3 and 12 months the mean migration was 0.07mm (95%CI: -0.16 to 0.32). There was no detectable wear on plain radiographs. We did not find any correlation between acetabular wear, patient weight or functional level.

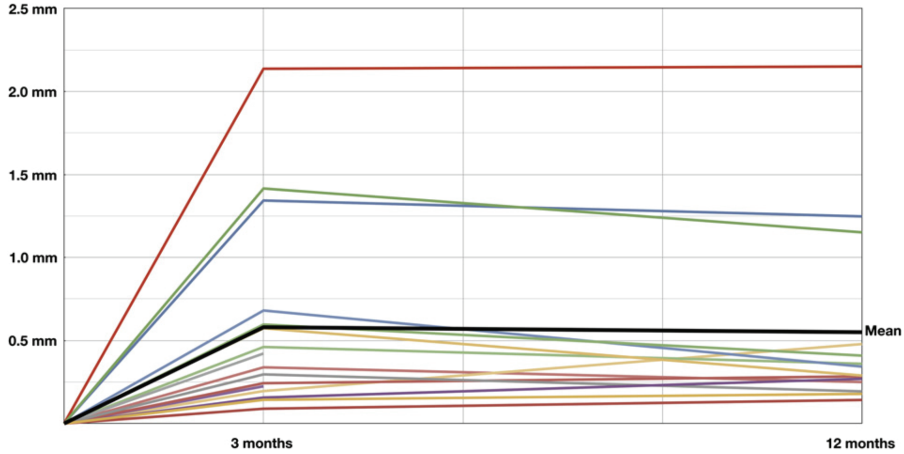

Figure 15: Graph showing 3D TPM of the center of the bipolar head in relation to pelvic markers

GENERAL DISCUSSION

Methods

Paper 1 is a study where we developed a new method on a series of consecutive patients and compared it with the “gold” standard for wear measurement in THR (Level II). The three studies[106-108] that make up the patient material for papers 2 and 3 were RCTs designed to evaluate new implants, as part of the “stepwise introduction of new hip implant technology” as described by Malchau[119]. Wear measurements were not the main objective of these studies, but all cups were marked to facilitate wear measurement. Our wear studies are retrospective cohort studies (Level III), strengthened by the fact that we had very good control of the cohorts and few patients lost to follow-up. Paper 4 is an RCT, but we found no difference in primary outcome variables, indicating that it might be underpowered for discovering any difference, or that longer follow up is needed. We have chosen to rate this as a Level II study. The strength of this study is that we showed that it is possible to use RSA to measure cartilage wear in the human body.

The main objective of papers 2 and 3 was to investigate the wear properties of two different head materials in THR. RSA is considered the most precise and accurate method currently available. Model-based RSA has a high impact on the cost of RSA studies for companies, because marking of the implants by attaching towers with tantalum beads is not an issue anymore. However, this method is not yet applicable without skeletal markers if implant motion in relation to bone is part of the study. A method using 3D surface models to represent bone has been reported by Seehaus et al.[120]. In its present form, the method does not have adequate precision and accuracy needed in all planes to replace marker based RSA fully. Secondly, we investigated the distribution of osteolysis on plain radiographs. This was done with software from mdesk (RSA Biomedical, Umeå, Sweden). The length of RLL between the cement/bone interface was measured in paper 2 and bone/cup in paper 3. We also measured the area of solitary osteolytic lesions. One obvious weakness of this method is that we measured a three-dimensional phenomenon (osteolysis) on two-dimensional images (AP pelvis). Other methods such as dual-energy x-ray absorbtiometry (DEXA) have been used in other studies[121-123], but this is also a two-dimensional examination, although it measures the full depth of the bone. In paper 2, bone cement was used which is known to complicate DEXA measurements, and in paper 3 the cups are screw-fixed which may also hamper the use of DEXA. CT-based osteodensiometry is also an alternative for quantitative assessment of periprosthetic bone[124]. CT technology is constantly improving, offering high-resolution images with less metal artifacts and lower radiation doses.

Clinical outcome was measured with HHS in paper 2, 3 and 4. This is a commonly used scoring tool in hip disease, both as a preoperative evaluation and at follow-up. It was designed for use on young men with often long-standing secondary osteoarthritis after an acetabular fracture, quite unlike the average 69-year old woman with primary arthrosis operated with THR in Norway today. There has been a concern for a ceiling effect in clinical follow-ups with HHS[125]. A ceiling effect occurs when a large proportion of the investigated subjects score the best possible score of a questionnaire. This indicates that the test isn´t challenging enough for the population that is tested. A ceiling effect should not exceed 15%[126].Another issue with HHS Is that it is clinician-scored; paving the way for intra- and inter observer bias[127]. Excluding the results from physical examinations as we did in paper 2, reduces the scoring to a non-validated modified evaluation. In patients operated for a femoral neck fracture, HHS seems to be a reasonable scoring tool[113]. We encountered ceiling effects for HHS in both paper 2 and 3. There are several available scoring systems for evaluation of clinical outcome after THR[128]. There is no consensus in the literature on which is the best. Some authors advocate using both a joint specific score such as the Oxford hip score[129], and a disease specific score such as the WOMAC[130]. These are both patient-reported outcome measures (PROM), and hence the problem of investigator bias could be avoided. Barthel Index and EQ-5D were used in paper 4; these are in contrast to HHS PROMs, and used to evaluate the overall health state of the patients and as such suitable for this population.

Results

The results from paper 1 demonstrated that our new method for wear measurement with RSA agree very well with conventional RSA measurements. The mean difference between the two methods were smaller than the detection limit (precision of RSA), the intraclass correlation coefficient was 0.96 for both proximal and 3D wear, so we are confident that there is no significant difference between the two methods for wear measurements in this material. The *center index method* can be applied without previous RSA examinations and without tantalum markers in hemispherical cups, if wear measurement is the only objective of a study. If implant migration in relation to bone is an issue; tantalum markers are still needed[131]. The method was developed using implants that are hemispherical, but it may also be possible to apply the same method to implants with a different shape. The center of a non-spherical cup could possibly be calculated by a model-based RSA technique in non-spherical cups and hence the method could be applied. We have not investigated this aspect.

The main outcome variable in paper 2 and 3 was PE wear after 10 years. This was measured as penetration of the center of the prosthetic head in the polyethylene cup/liner and presented as proximal (y-axis) and 3D (the vector of all three cardinal axes (x^2+y^2+z^2)) with RSA. We found approximately 50% wear reduction with alumina heads compared to CoCr heads in both studies and the mean difference was highly significant in both studies. This is in accordance with hip simulator studies[37,38,71]. *In vitro* studies are necessary to evaluate wear behaviour under standardized conditions, but they can never replace clinical studies. In the clinical setting, there are two methods for wear measurement; retrieval- and radiological studies. One retrieval study with 67 cups (30 alumina and 37 metal, all 32 mm heads) reported less wear in the group with alumina heads (0.13 mm/y vs 0.19 mm/y)[132], another study repored comparable results in 4 cups[133], and one study found inferior results for alumina heads in 32 cups[134]. Clinical studies that directely compare wear properties of alumina- and metal heads on PE are rare in the literature. Schüller and Marti (1990) reported 0.26 mm wear for alumina heads and 0.96 mm for metal heads (Protasul) after 9-11 years in 66 patients with a Weber type cemented THR with 32 mm heads. Measurements were conducted on standing radiographs, and the migration of the center of the femoral head in relation to the metallic ring in the cup was measured[135]. Zichner and Willert (1992) found superior wear properties for alumina compared to Protasul-2 and Protasul-10 heads all on PE, on plain radiographs with a method similar to Charnley[83]. They reported that 95% of hips with alumina heads had less than 0.2 mm wear, while the result for Protasul-2 and 10 were 64% and 77% respectively[136]. Clarke and Gustavson (2000) reported 50% wear reduction with alumina heads compared to metal heads, both in simulators and in a clinical setting[71]. The same refers to a study by Wroblewski et al (1996), reporting 0.057 mm/y wear of 22 mm alumina heads on cross-linked PE with a method developed by Collins[137]. They found comparable results to simulator studies of the same coupling[138]. Sychters et al. (2000) compared 81 alumina heads with a well matched group of 43 CoCr heads with a manual method on AP films[139]. Both groups had 32 mm diameter heads. Mean follow-up was 7 years (4-10) and mean wear was 0.07 mm per year for CoCr heads and 0.09 mm for alumina heads. Recently, Wang et al. (2013) published a study of 22 patients who were operated with simultanous bilateral THR. One side was operated with an alumina head and one side with a CoCr head in all cases, otherwise the components were identical. They found less wear with alumina heads (0.056 mm/year) than with CoCr heads (0.133 mm/year) ($p<0.001$)[140]. Wear was measured with a method described by Dorr and Wang[141]. Jung and Kim (2010) identified 19 studies that report wear results on alumina on PE[142]. There is of course a mix of components, manufacturers, head sizes and measuring methods in this review. Linear wear rates ranged from 0.019 to

0.33 mm/year. The least wear were from a study with 22 mm heads on cross linked PE and might not be representative as smaller heads wear less than larger heads[57], and cross-linked PE wear less than conventional PE[143]. The most wear was found in a study with Hylamer PE, which has shown inferior wear properties[144]. We used a precise and accurate measuring method and therefore believe that our results are valid. We observed more wear in the uncemented liners in paper 3 compared to the cemented cups in paper 2. This is in accordance with Mccombe et al. (2004) who found a yearly wear rate of 0.15 mm in uncemented cups compared to 0.07 mm in cemented cups ($p<0.001$) in a RCT using the Livermore method for wear measurement[145]. Bjerkholt et al. (2010) found comparable wear rates for cemented and uncemented cups (1.07mm vs 1.18mm) ($p=0.59$) after 9-10 years with the same PE with the Livermore method.

A secondary outcome measure in paper 2 and 3 was periacetabular osteolysis. In paper 2 we found a tendency towards more RLL in patients with CoCr heads compared to patients with alumina heads, but the difference was not significant except for one Charnley/Delee zone, and we had only fair agreement between different observers. Investigating RLL between cement and bone might not be the ideal method for quantification of bone loss in cemented cups. We found 1 patient with a solitary osteolytic lesion larger than 10 mm^2 in the CoCr group compared to zero in the alumina group. Hence, we did not find any significant correlation between increased wear and amount of osteolysis in cemented cups. This is in accordance with one recent study[146] comparing cross-linked and conventional PE; wear reduction did not lead to reduced revision rate. In paper 3, we found a numerically, but not significant larger area of osteolysis in the CoCr group than in the alumina group (30 mm^2 vs 22 mm^2 (p=0.2)). We did not find any difference in the distribution of RLL between the groups in that study. There was no correlation between increased wear and revision rate in paper 2 and 3. We did not find any difference in clinical outcome measured with modified HHS in paper 2. In paper 3 we found a significant correlation between low wear and a higher HHS. Patients with alumina heads scored 98 points and patients with CoCr heads scored 93 at the 10-year follow-up (p= 0.01). HHS is vulnerable to a ceiling effect as many patients score 100 points. The difference was however still significant when we dichotomized the results to *top score* and *not top score*. Whether a difference of 5 points in HHS after 10 years is clinically meaningful is debatable, but in this study it seemed to be an advantage to be in the group with alumina heads since they had lower PE wear, higher HHS and a tendency to less osteolysis. The results from this study can probably not be used to conclude that patients with alumina heads in general do better than patients with CoCr heads.

The main objective in paper 4 was to investigate whether RSA could be used to measure cartilage wear in the acetabulum after bipolar HA. The phantom study showed a mean error of elliptical fitting of the edge of the bipolar head of 0.024 mm calculated from eight double examinations. This means that we are able to determine the center of the head precisely[147]. We also confirmed that rotation of the bipolar head did not affect the position of the center of the heads relation to the pelvic markers, as the ability to measure zero migration between repeat examinations after having moved the bipolar head was 0.195 mm for total point motion. The clinical study demonstrates the possibility for precise measurement of cartilage wear since the mean differences between double examinations were small; 0.024 mm for the x-axis, -0.019 mm for the y-axis, and -0.013 for the z-axis. We measured a mean 3D wear of 0.62 mm at 3 months for the whole group and a further negative wear of 0.07 mm from 3 to 12 months. We did not find any difference between cemented and uncemented stems. Jeffcote et al (2010) published a comparable study on unipolar vs. bipolar HA[148]. They reported 3D wear results that are comparable to our study (0.62 mm at 24 months vs. 0.55 mm at 12 months) for bipolar HA, but more wear for unipolar HA (1.52 mm at 12 months). Baker et al (2006) reported 66% acetabular erosion after HA and introduced a grading system for acetabular wear that has been used by other authors[149]. We believe that RSA provides a more precise and accurate measurement for acetabular wear. One study reported significantly more acetabular erosion in unipolar versus bipolar HA[150] in an elderly population with femoral neck fractures, and one study reported that 60% of bipolar heads migrated more than 5 mm in a younger population at a mean of 10.4 years[151]. We did not find any difference in clinical outcome between the groups, but our study was probably underpowered to find any difference in outcome if present. The clinical outcome was however comparable to the larger RCT that some of the patients were recruited from[109].

CONCLUSIONS

1. Alumina heads induce less PE wear than CoCr heads in both cemented and uncemented acetabular components measured with RSA. (Paper 2 and 3)

2. There was no significant correlation between the amount of PE wear and measurable osteolysis on AP radiographs up to 10 years. (Paper 2 and 3)

3. We found no correlation between increased wear and revision rate. (Paper 2 and 3)

4. Polyethylene wear can be measured with RSA with no previous stereoradiographs in hemispherical cups after THR. (Paper 1)

5. RSA can be used to measure cartilage wear after HA. (Paper 4)

SUGGESTIONS FOR FURTHER RESEARCH

1. Difference in wear between ceramic and metal heads of different diameters articulating with modern cross-linked PE should be investigated in a RCT with a high precision measuring method (RSA). The method is important since very low wear rates must be expected in these articulations.

2. Development of measuring methods to determine osteolysis that are more sensitive and less investigator dependent than the method we used. New software for CT-based methods are developed with lower radiation doses and improved ability to remove metal artifacts are promising.

3. The center index method we present in paper 3 facilitate retrospective follow-up of cohorts with a high precision measuring method for wear. Such follow-ups would be valuable to monitor the performance of cross-linked PE.

NORSK SAMMENDRAG

Målet med denne doktorgraden er todelt. To av artiklene (nr 2 og 3) tar for seg slitasje av hofteproteser. En hofteprotese kan sees på som en mekanisk kobling mellom bekkenet og lårbenet. Vi har undersøkt om det er forskjell mellom polyetylenslitasje (plastslitasje) i hofteproteser med protesehoder av keramikk (alumina) og protesehoder av metall (kromkobolt). Vi fant at bruk av keramikkhoder reduserer slitasjen til det halve etter ti år målt med radiostereometri (RSA), som er den mest nøyaktige og presise målemetoden. Imidlertid fant vi ingen forskjell i beintap rundt protesene, reoperasjonsrate eller funksjonsnivå mellom gruppene. Det kan være at ti år er for kort oppfølgingstid for at slitasjeforskjellen skal manifestere seg i bedret klinisk resultat.

De to andre artiklene (nr 1 og 4) omhandler målemetoder for slitasje av totalproteser og halvproteser (kun protese i lårbenet etter lårhalsbrudd). I den ene (nr 1) viser vi at det er mulig å måle plastslitasje uten at vi har stereorøntgenbilder fra postoperative undersøkelser tilgjengelig. Det gjør vi ved at i stedet for å måle hvor sentrum av protesehodet befant seg postoperativt, beregner vi hvor det var ved å anta at det var i sentrum av protesekoppen. Vi sammenlignet våre funn med funnene fra undersøkelsen der vi målte hvor protesehodet var etter operasjonen og fant at metodene samsvarte meget bra. I den siste studien (nr 4) viser vi at det er mulig å måle bruskslitasje i hofteskålen etter operasjon med halvprotese på grunn av lårhalsbrudd. Vi kalkulerte sentrum av protesehodet og målte bevegelsen av dette i forhold til markører vi implanterte i bekkenet, og definerte dette som slitasje. Først gjorde vi en fantomstudie med plastbein for å se at vi fikk presis nok fremstilling av protesehodet, og at det ikke hadde betydning for posisjonen av sentrum av protesehodet at vi roterte protesehodet i forhold til hofteskålen. Deretter gjorde vi en studie på pasienter der vi ikke fant noen forskjell mellom sementerte og usementerte protesestammer, hverken med hensyn til slitasje eller klinisk resultat.

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Appendix 1 – Harris Hip Score

Harris Hip Score

I. Pain (44 points possible)

A. None or ignores it	44
B. Slight, occasional, no compromise in activities	40
C. Mild pain, no effect on average activities, rarely moderate pain with unusual activity, may take aspirin	30
D. Moderate pain, tolerable but makes concessions to pain. Some limitation of ordinary activity or work. May require occasional pain medicine stronger than aspirin	20
E. Marked pain, serious limitation of activities	10
F. Totally disabled, crippled, pain in bed, bedridden	0

II. Function (47 possible)

A. Gait (33 points possible)

1. Limp	
a. None	11
b. Slight	8
c. Moderate	5
d. Severe	0
2. Support	
a. None	11
b. Cane for long walks	7
c. Cane most of the time	5
d. One crutch	3
e. Two canes	2
f. Two crutches	0
g. Not able to walk (specify reason)	0
3. Distance walked	
a. Unlimited	11
b. Six blocks	8
c. Two or three blocks	5
d. Indoors only	2
e. Bed and chair	0

B. Activities (14 points possible)

1. Stairs	
a. Normally without using a railing	4
b. Normally using a railing	2
c. In any manner	1
d. Unable to do stairs	0
2. Shoes and Socks	
a. With ease	4
b. With difficulty	2
c. Unable	0
3. Sitting	
a. Comfortably in ordinary chair for 1 h	5
b. On a high chair for 0.5 h	3
c. Unable to sit comfortably in any chair	0
4. Enter public transportation	1

III. Range of motion and absence of deformity (9 points possible)

A. Flexion	
0° to $>90^\circ$	3
$0–90^\circ$	2
0° to $<90^\circ$	1
0°	0
B. Abduction	
$>20^\circ$	2
$<20^\circ$	1
0°	0
C. Deformity	
None	4
$>30^\circ$ fixed flexion contracture	0
$>10^\circ$ fixed adduction	0
$>10^\circ$ fixed internal rotation in extension	0
Limb-length discrepancy >3 centimetres	0

Appendix 2 – Barthel Index

Barthel Index of Activities of Daily Living

Instructions: Choose the scoring point for the statement that most closely corresponds to the patient's current level of ability for each of the following 10 items. Record actual, not potential, functioning. Information can be obtained from the patient's self-report, from a separate party who is familiar with the patient's abilities (such as a relative), or from observation. Refer to the Guidelines section on the following page for detailed information on scoring and interpretation.

The Barthel Index

Bowels
0 = incontinent (or needs to be given enemata)
1 = occasional accident (once/week)
2 = continent
Patient's Score: _____________

Bladder
0 = incontinent, or catheterized and unable to manage
1 = occasional accident (max. once per 24 hours)
2 = continent (for over 7 days)
Patient's Score: _____________

Grooming
0 = needs help with personal care
1 = independent face/hair/teeth/shaving (implements provided)
Patient's Score: _____________

Toilet use
0 = dependent
1 = needs some help, but can do something alone
2 = independent (on and off, dressing, wiping)
Patient's Score: _____________

Feeding
0 = unable
1 = needs help cutting, spreading butter, etc.
2 = independent (food provided within reach)
Patient's Score: _____________

Transfer
0 = unable – no sitting balance
1 = major help (one or two people, physical), can sit
2 = minor help (verbal or physical)
3 = independent
Patient's Score: _____________

Mobility
0 = immobile
1 = wheelchair independent, including corners, etc.
2 = walks with help of one person (verbal or physical)
3 = independent (but may use any aid, e.g., stick)
Patient's Score: _____________

Dressing
0 = dependent
1 = needs help, but can do about half unaided
2 = independent (including buttons, zips, laces, etc.)
Patient's Score: _____________

Stairs
0 = unable
1 = needs help (verbal, physical, carrying aid)
2 = independent up and down
Patient's Score: _____________

Bathing
0 = dependent
1 = independent (or in shower)
Patient's Score: _____________

Total Score: _______________

Appendix 3 – Eq-5d

EQ-5D (UK English version)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about	❑
I have some problems in walking about	❑
I am confined to bed	❑

Self-Care

I have no problems with self-care	❑
I have some problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities	❑
I have some problems with performing my usual activities	❑
I am unable to perform my usual activities	❑

Pain/Discomfort

I have no pain or discomfort	❑
I have moderate pain or discomfort	❑
I have extreme pain or discomfort	❑

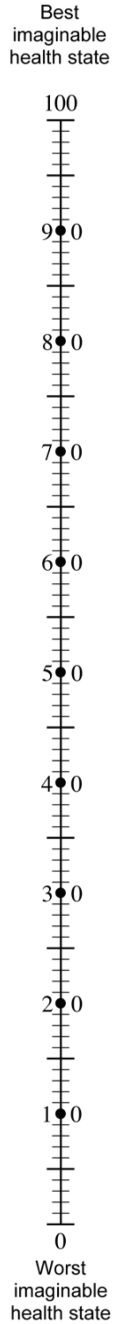
Anxiety/Depression

I am not anxious or depressed	❑
I am moderately anxious or depressed	❑
I am extremely anxious or depressed	❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Appendix 4 – Papers 1-4

1

2

3

More than 50% reduction of wear in polyethylene liners with alumina heads compared to cobalt-chrome heads in hip replacements

A 10-year follow-up with radiostereometry in 43 hips

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Background and purpose Excessive wear of acetabular liners in hip replacements may lead to osteolysis and cup loosening. Different head materials are currently used. We measured differences in wear between alumina and cobalt-chrome heads with the same polyethylene liner.

Patients and methods 39 patients (43 hips) with osteoarthritis were included in a study with 10-year follow-up. Wear was measured as proximal and 3D penetration of the head in the liner with radiostereometry (RSA). All the patients were followed clinically with Harris hip score (HHS) for up to 10 years. Radiolucent lines and osteolytic lesions were assessed on plain radiographs.

Results With alumina heads, proximal wear (95% CI) after 10 years was 0.62 (0.44–0.80) mm as compared to 1.40 (1.00–1.80) mm in the cobalt-chrome group. For 3D wear, the results were 0.87 (0.69–1.04) mm for alumina heads and 1.78 (1.35–2.21) mm for cobalt-chrome heads. Median (range) HHS was 98 (77–100) in the alumina group and it was 93 (50–100) in the cobalt-chrome group (p = 0.01). We found no difference in osteolysis between the groups.

Interpretation We found better wear properties with alumina heads than with cobalt-chrome heads. We recommend the use of alumina heads in patients in whom a high wear rate might be anticipated.

Polyethylene (PE) wear is a major limitation for long-term survival of total hip replacements (THRs). Production of wear particles induces osteolysis and leads to aseptic loosening of the implant (Dumbleton et al. 2002, Wilkinson et al. 2005, Purdue et al. 2006). Dumbleton et al. (2002) suggested that the threshold for acceptable linear wear should be 0.1 mm per year and that osteolysis is almost non-existent if wear is reduced to below 0.05 mm per year. They also reported that osteolysis and loosening increases if the wear rate is more than 0.2 mm/year.

The problem of wear has been addressed in different ways, such as head size and material choice. The use of smaller femoral heads reduces wear (Kesteris et al. 1996), but it increases dislocation-rate (Bystrom et al. 2003) and reduces range of motion (Burroughs et al. 2005). Different bearing surfaces such as ceramic-on-ceramic have low wear rates, but they have other disadvantages such as nano-sized wear particles, breakage, chipping, and squeaking (Keurentjes et al. 2008, Lang et al. 2008). Breakage of ceramic heads has been reported to range from 0.004% to 13% (Willmann 2000, Allain et al. 2003). A well-functioning ceramic head is thought to give less wear than a metal head when coupled with PE, because of a smoother surface and better wettability (Saikko et al. 2001, Hannouche et al. 2011). Metal-on-metal bearings have low wear rates, but reports from international registries have shown higher revision rates for resurfacing THR than for conventional THR.

Wear is related to activity (Schmalzried et al. 2000) and therefore young and active patients could possibly have higher prosthesis wear. Other factors that may have an influence on wear rates in THR are cup positioning, implant fixation method, implant material, and coating of implant. Possible patient factors are weight, age, gender, and level of activity.

The aim of this study was to investigate a possible difference in wear patterns between 2 different head materials (cobalt-chrome and alumina) of the same size (28 mm) articulating on liners made of identical PE in the same type of acetabular shell. Metal heads such as cobalt-chrome are cheap, durable, and well proven with PE acetabular components (Furnes et al. 2007). Other materials should be as safe and should have

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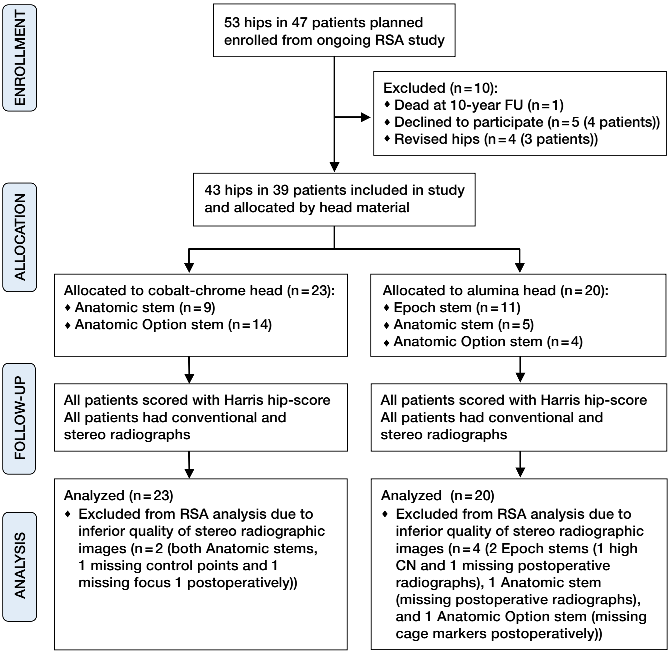

CONSORT 2010 flow diagram.

durability superior to that of metal heads, to replace them as the material of choice for use with PE in THR. One RSA study showed better wear properties for alumina heads than for cobalt-chrome heads with cemented cups (Dahl et al. 2012). Another study showed the opposite with uncemented cups (Sychterz et al. 2000).

Patients and methods

The cohort we studied was recruited from a randomized controlled multicenter study (Karrholm et al. 2002). In the original study, 53 hips in 47 patients were operated with total hip replacement (THR). 39 patients (43 hips) were included in the present study (Figure). In all patients, the indication was primary or secondary osteoarthritis without anatomical abnormalities. The patients were randomized to 3 groups. All of them received a Trilogy acetabular component. This is a hemispheric porous-coated (titanium mesh) cup with a polyethylene liner (compression-molded GUR 1050; Ticona, Summit, NJ) sterilized with γ-irradiation in nitrogen. All patients received the same liner material, but the liner thickness varied with the shell size. All cups were also fixated with 2–3 screws. On the femoral side, the patients were randomized to either Epoch, Anatomic, or Anatomic Option (Zimmer, Warsaw, IN). Epoch is a porous-coated composite stem with reduced stiffness, Anatomic is a proximally porous-coated titanium alloy stem, and Anatomic Option is a cemented cobalt-chrome (Zimaloy) stem. Palacos bone-cement (Schering Plough; Labo N.V., Belgium) was used in all the cemented cases. The uncemented stems had additional plasma-sprayed hydroxyapatite-tricalcium phosphate coating. All Epoch stems had alumina heads (Biolox Forte; CeramTec, Plochingen, Germany). 29 of 38 Anatomic and Anatomic Option stems had cobalt-chrome heads; 9 had the same alumina heads as the Epoch stems. The intention was to operate all patiaents in the study with alumina heads, but this was changed because the approval for these heads on the taper of the Anatomic stems was withdrawn. After this withdrawal, all Anatomic stems received cobalt-chrome heads. The same surgeon (FS) operated most patients and was present at all operations. The groups were comparable with regard to age, sex, weight, side, cup size, liner thickness, and preoperative Harris hip score (Table 1).

Clinical outcome

All patients were scored with the Harris hip score preoperatively, and this examination was repeated after 10 years. Revisions and reasons for these were noted.

RSA

Index RSA was acquired with analog technique and measuring cage 41 (RSA Biomedical, Umeå, Sweden). The analog radiographs were scanned (Scanmaker 9800xl; Microtec Lab. Inc., Cerritos, CA), digitized, and re-marked with digital

Table 1. Description of patients and groups

	Cobalt-chrome	Alumina
n	23	20
Age at operation [a]	60 (53–72)	64 (34–70)
Sex, M/F	6/17	9/11
Weight at operation [a]	70 (58–98)	78 (51–95)
Preoperative Harris hip score [a]	52 (28–69)	55 (25–67)
Side, left/right	11/12	8/12
Cup size [a]	52 (48–60)	54 (50–60)
Liner thickness [a]	7.3 (6.3–10.4)	7.3 (7.3–10.4)
Stem type		
Epoch	0	11
Anatomic option	14	4
Anatomic	9	5

[a] Median (range)

Table 2. Mean migration of the center of the prosthetic head, in mm, in relation to the cup measured with RSA, significance level for difference, and precision of measurements from 71 double examinations. 95% CI of mean in parentheses and range in square brackets

Direction	Cobalt-chrome			Alumina			p-value	Precision
Proximal (y-axis)	1.40	(1.00 to 1.80)	[0.38 to 3.6]	0.62	(0.44 to 0.80)	[0.23 to 1.33]	0.001	0.09 (0.06–0.11)
Medial (x-axis)	–0.38	(–0.72 to –0.04)	[–1.81 to 0.67]	–0.10	(–0.27 to –0.08)	[–0.76 to 0.26]	0.2	0.11 (0.08–0.14)
Posterior (z-axis)	–0.59	(–0.84 to –0.34)	[–1.64 to 0.82]	–0.32	(–0.54 to –0.10)	[–0.94 to 0.37]	0.1	0.18 (0.13–0.23)
3D (x-, y-, and z-axis)	1.78	(1.35 to 2.21)	[0.62 to 4.3]	0.87	(0.69 to 1.04)	[0.33 to 1.49]	< 0.001	Not applicable

technique using UmRSA digital measuring software version 6.0 (RSA Bomedical). 10-year RSA was acquired digitally using measuring cage 43 and the same software as used for the index RSA. The acetabular components were also marked and measured using markerless technique (Borlin et al. 2006). The Trilogy cup is a hemisphere, and therefore the center of the hemisphere can be found using edge-detection methods. Linear wear was measured as penetration of the center of the head in the cup along the vertical (y-) axis and as a vector of all 3 axes (x-, y-, and z-axis). Cup movement was measured as migration and rotation of the cup in relation to the acetabular markers. Precision was determined from 71 double examinations as absolute mean difference (95% CI of the mean) between the double examinations postoperatively and after 10 years (Table 2). We included examinations with condition number (CN) below 120 and mean error below 0.3 in the study, as this is generally accepted to be adequate quality for RSA measurements (Valstar et al. 2005).

Radiography

All patients had conventional radiographs taken at 10 years. These were analyzed using mdesk (RSA Biomedical). This software allows measurement of implant positioning, distribution of radiolucent lines (RLLs) between cup and pelvis, and osteolytic lesions. RLLs wider than 1 mm in the AP view were measured. Osteolytic lesions were measured in mm^2 on the AP radiograms. Cup positioning in relation to pelvic landmarks was also determined.

Statistics

A mixed-model analysis was performed for difference in wear between groups since we had 2 patients with bilateral implants in the final wear analysis, thus not being independent observations. The regression analysis was done with xtreg in Stata software version 11.0. The significance level was set to p = 0.05 for differences between groups. We used Pearson's correlation coefficient to check for correlation between continuous variables. Calculations were done using the PASW statistics package version 18.

Ethics

The study was conducted in accordance with the Helsinki Declaration. The regional ethical committee in Norway approved the study (REK Sör S-93122).

Results

Clinical outcome

There were 2 revisions in each group at 10 years. In the alumina group, 1 patient with bilateral Epoch stems was revised on both sides due to pain. She had measurable wear in both hips, but not enough to be revised for this reason alone. In the cobalt-chrome group, 1 patient was revised due to stem loosening and 1 was revised because of inexplicable pain. Both had Anatomic Option stems. Median (range) Harris hip score after 10 years was 93 (50–100) in the cobalt-chrome group and 98 (77–100) in the alumina group (p = 0.01).

RSA

RSA analyses were performed on patients who had radiographs of adequate quality postoperatively and after 10 years. This left us with 21 patients in the cobalt-chrome group and 16 in the alumina group. We found more than 50% reduction of head penetration (wear) both proximally and in 3D in the alumina group, compared to the cobalt-chrome group. The mean difference (95% CI) between the groups was 0.78 (0.34–1.22) mm for proximal wear and 0.91 (0.44–1.38) mm for 3D wear. Wear was measured for both groups along all axes (Table 2). We found no statistically significant difference in wear between the subgroups with different stems and fixation methods. There was also no statistically significant difference between men and women or between younger and older patients (i.e. less than or more than 60 years of age at operation) in this material. All cups were found to be stable.

Radiography

Mean area of osteolysis (95% CI) was 30 (21–39) mm^2 in the cobalt-chrome group and 22 (14–30) mm^2 in the alumina group (p = 0.2). 2 of 23 cases had no osteolysis in the cobalt-chrome group, as compared to 3 of 20 cases in the alumina group.

Most osteolytic lesions were found in the area of screw fixation. There was no significant difference in the distribution of radiolucent lines between the 2 groups. We found no systematic bias in cup positioning in relation to the pelvis between the groups.

Discussion

We found more than 50% reduction in wear for alumina heads on conventional polyethylene liners compared to cobalt-chrome heads. This is of considerable interest, as wear is a major reason for aseptic loosening and osteolysis in hip-replacement surgery. This study was conducted using conventional polyethylene, which is less wear-resistant than modern crosslinked polyethylene (Rohrl et al. 2007). Use of alumina heads instead of cobalt-chrome heads on modern polyethylene could reduce wear even further. The difference in wear between alumina and cobalt-chrome heads may also be less when articulating with crosslinked polyethylene. We found no statistically significant difference in osteolysis, although there was a tendency of more osteolysis in the cobalt-chrome group. 10 years may be too short a follow-up time for increased wear to manifest itself as increased osteolysis. Our findings do not support the so-called threshold for tolerable linear wear of 0.1 mm per year. The cobalt-chrome group had a wear pattern well above this threshold and the alumina group a wear pattern well below this threshold, but we did not find any difference in survival or osteolysis up to 10 years. A tendency of increased osteolysis and reduced clinical outcome at 10 years could be an indication for earlier failures in this group in future. Even though we found wear reduction of more than 50% for alumina heads and a tendency of less osteolysis in the alumina group, we cannot say that this was clinically significant after 10 years as there was no difference in the number of revisions between the groups. This has also been reported in the Australian joint registry, where revision rates of THRs with ceramic and metal heads articulating on modified PE have been compared; results with conventional PE have not been compared (Graves 2011).

The number of patients was too small to trust the observed difference in clinical outcome in our material. There were also substantial confounders to this finding, such as different stems and fixation methods. The Harris hip scores were generally high in both groups. The patients in our study were 61 years old on average at operation, and they will use their prosthesis for far more than the 10 years covered here.

The present study had several strengths. The patients were recruited from a randomized trial of stem fixation with RSA, so we had good check of the patients, and only 5 of them were lost to follow-up at 10 years. 1 investigator performed the clinical follow-up for all patients. Conventional radiographs were investigated in addition to RSA, for possible explanations of difference in wear other than head material—such as offset, height of hip center, and cup inclination—and to evaluate bone loss and signs of loosening of cups and stems. The reduction in wear was highly significant even though the number of patients was small.

The weaknesses of our study were that it was not originally designed to study wear, and that randomization was not done by head material, but by stem type. Thus, different stems and fixation methods were used on the femoral side. One might speculate that this could have an influence on the wear of the articulation. We found no difference in wear whether patients in the alumina group had Epoch or Anatomic/Anatomic Option stems. There was also no difference in wear between Anatomic and Anatomic Option stems in the cobalt-chrome group. This indicates that stem type is not a major confounder. When we break this material down, the subgroups become very small with only a few patients in each group; therefore, it is probably underpowered with regard to analysis of subgroups such as high/low BMI, men/women, and young/old patients. RSA examinations were obtained with different calibration cages and with analog technique postoperatively but digital technique at 10 years. We used markerless technique for our wear measurements; this relies on using the contour of the femoral head to calculate the center of the head. This contour is easier to determine on the more radiopaque cobalt-chrome heads, but we found no statistically significant difference in precision between the head materials. We had problems with a lack of visible markers and poor spread of markers in the acetabular segment, which was a limitation regarding the evaluation of cup stability. The patients had no clinical signs of cup loosening up to 10 years, and we found no large osteolytic lesions on conventional X-rays. We therefore considered the cups to be stable despite this limitation. The study was performed with conventional polyethylene. Most hip-replacement surgeons have changed their practice and have left this socket material in favor of modern crosslinked PE.

In summary, we found more than 50% wear reduction when using alumina heads rather than cobalt-chrome heads in this study. We recommend the use of this head material in patients in whom a high wear rate might be anticipated.

JD: wrote the manuscript, collected clinical data, performed analyses with RSA and mdesk, and performed statistical analyses. FS: planned the study, operated most of the patients, contributed to the radiographic analyses, and proofread the manuscript. LN: planned the study and proofread the manuscript. SMR: contributed to writing of the manuscript and contributed to both the RSA analyses and the statistical evaluation.

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No competing interests declared.

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